Reimbursement Steering Committee
Highlights of 2006 Proposed Rule for Physician Fee Schedule

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule [Federal Register / Vol. 70, No. 151 / Monday, August 8, 2005 / pp. 45764-46064]

Refer to the full text of the Proposed Rule for more information

Comments on the Proposed Rule must be received by 5 PM September 30, 2005

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I. Background (pp. 45766 - 45767)

A. Introduction (p. 45766)

The Social Security Act requires that payments under the physician fee schedule (PFS) be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. The Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense.

Prior to the 1992 establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges.

B. Development of the Relative Value System (pp. 45766 -45767)

This section describes the history of the implementation of resource based RVUs.

1. Work RVUs

Physician work RVUs were established in 1992. Initially, only the physician work RVUs were resource-based, and the PE and malpractice RVUs were based on average allowable charges.

2. Practice Expense RVUs

The Act initially required that CMS establish resource-based Practice Expense RVUs in 1998, but was amended to delay implementation until 1999 and phase in over a four-year transition period from 1999 through 2002.

Separate PE RVUs are established for procedures that can be performed in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department. The difference between the facility and nonfacility RVUs reflects the fact that a facility receives separate payment from Medicare for its costs of providing the service, apart from payment under the PFS. The nonfacility RVUs reflect all of the direct and indirect practice expenses of providing a particular service.

3. Malpractice RVUs

CMS implemented resource-based malpractice RVUs for services furnished on or after 2000 based on malpractice insurance premium data.

4. Refinements to the RVUs

The Act requires that CMS review all RVUs no less often than every five years. The first and second five year reviews for physician work RVUs went into effect in 1997 and 2002. The next 5-year review for physician work RVUs is scheduled to go into effect in 2007. Through March of 2004, the AMA's RUC/PEAC (Practice Expense Advisory Committee) provided recommendations to CMS for over 7600 codes for the purpose of refining the direct PE inputs. In the November 15, 2004 PFS final rule CMS implemented the first 5-year review of the malpractice RVUs.

5. Adjustments to RVUS are Budget Neutral

The Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have been if the adjustments were not made.

C. Components of the Fee Schedule Payment Amounts (p. 45767)

The general formula for calculating the Medicare fee schedule amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x CF.

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D. Most Recent Changes to the Fee Schedule (p. 45767)

Changes from November 15, 2004 PFS Final Rule:

- Refined the resource-based PE RVUs
- Supplemental survey data for PE;
- Updated GPCIs for physician work and PE;
- Updated malpractice RVUs;
- Revised requirements for supervision of therapy assistants;
- Revised payment rules for low osmolar contrast media;
- Payment policies for physicians and practitioners managing dialysis patients;
- Clarification of care plan oversight (CPO) requirements;
- Requirements for supervision of diagnostic psychological testing services;
- Clarifications to the policies affecting therapy services provided incident to a physician's service;
- Requirements for assignment of Medicare claims;
- Additions to the list of telehealth services;
- Changes to payments for drug administration services; and
- Several coding issues.

Changes from November 15, 2004 PFS Final Rule that are Related to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA):

- Coverage of an initial preventive physical examination.
- Coverage of cardiovascular screening blood tests.
- Coverage of diabetes screening tests.
- Incentive payment improvements for physicians in physician shortage areas.
- Changes to payment for covered outpatient drugs and biologicals and drug administration services.
- Changes to payment for renal dialysis services.
- Coverage of routine costs associated with certain clinical trials of category A devices as defined by the Food and Drug Administration.
- Coverage of hospice consultation service.
- Indexing the Part B deductible to inflation.
- Extension of coverage of intravenous immune globulin (IVIG) for the treatment in the home of primary immune deficiency diseases.
- Revisions to reassignment provisions.
- Payment for diagnostic mammograms.
- Coverage of religious nonmedical health care institution items and services to the beneficiary’s home.

Other Changes from November 15, 2004 PFS Final Rule:

- Finalized the calendar year (CY) 2004 interim RVUs for new and revised codes in effect during CY 2004
- Issued interim RVUs for new and revised procedure codes for CY 2005;
- Updated the codes subject to the physician self-referral prohibition;
- Discussed payment for set-up of portable x-ray equipment;
- Discussed the third 5-year refinement of work RVUs;
- Solicited comments on potentially misvalued work RVUs.
- Announced that the PFS update for CY 2005 would be 1.5 percent; and that the initial estimate for the sustainable growth rate for CY 2005 is 4.3; and the CF for CY 2005 is $37.8975**.**

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II. Provisions of the Proposed Rule (pp. 45767 – 45857)

A. Resource-Based Practice Expense Relative Value Units (RVUs) (pp. 45768 -45783)

This section provides a history of how the Relative Value Units started and how it changed physician payment from historical allowed charges to the RVUs that are defined today. As of March 2004, the AMA's RUC, which established the Practice Expense Advisory Committee (PEAC) has provided recommendations for over 7600 codes. Now the PEAC has been replaced by the Practice Expense Review Committee (PERC) which assists the RUC in recommending PE inputs.

The current approach to the PE RVUs is referred to as "top down." The “top down” approach allocates aggregate specialty practice costs to specific procedures. It takes the PE per hour/60 to get PE per minute. Then multiples the physician time, number of times performed (services) by the PE minute.

The subtotal of the above is then added to the all other services category, which gives us the total for the SMS (Socioeconomic Monitoring System) Pool.

Calculation of the CPEP (Clinical Practice Expert Panel) Cost Pool is made when the clinical labor costs for a procedure are multiplied by the number of services provided by the specialty. The subtotal is then added to all other services, and we received the total CPEP Pool.

Scaling factors are then applied to ensure that the total of the CPEP costs across all procedures performed by the specialty equates with the total direct costs for the specialty as reflected by the SMS data.

Indirect expenses (rent, legal fees, etc.) are calculated by summing the scaled direct expenses and the converted work RVU (multiplied by 34.5030) and then multiplying by the number of services provided by the specialty. The total indirect PEs per specialty are calculated by summing the indirect expenses for all other procedures provided by that specialty.

Scaling factors are then also applied to the indirect costs, as they were to the direct costs above. This is followed by calculating the weighted average for codes that are performed by more than one specialty.

When the total scaled direct and indirect inputs are calculated, they are then adjusted by the budget neutrality factor to calculate the RVUs.

For services which do not have physician work a separate PE pool has been formed until CMS can further analyze the effect of the above methodology on these services. The steps are basically the same as for the physician pool with some (but not limited to) exceptions, such as substituting physician time for clinical staff time to get the SMS Cost Pool and using the 1998 (charge based) PE RVU value for calculating charge-based PR RVU Cost Pool. As above, scaling factors are then applied.

Indirect expenses are set equal to direct expenses, and then multiplied by the number of times the procedure is performed. Scaling factors are then applied and final RVU calculation is made with budget neutrality.

Practice Expense Proposals for 2006

Submission deadline for supplemental PE surveys was March 1, 2005. For those surveys that were submitted in 2004, the American College of Cardiology (ACC) and American College of Radiology surveys were accepted. However, CMS deferred using their data until issues related to the non-physician work pool could be addressed. For those surveys submitted in 2005, the Lewin Group did their evaluation and found that all submitted (except the National Coalition of Quality Diagnostic Imaging Services (NCQDIS)) met the approved criteria and CMS is proposing to accept them.

CMS is proposing to now calculate PEs using the "bottom up" methodology. The goals for the revision to the PE methodology are to ensure the PE payments reflect the actual relative resources required for each service, to develop a payment system that is understandable and intuitive, and to stabilize PE payments.

This methodology would allow for the direct costs to be determined by summing the costs of the resources required to provide the service. It would also eliminate the non-physician work pool, and bring their methodology into alignment with the physician group. They would utilize the current indirect PE RVUs (except

those accepted in the supplemental survey) and anticipated that this transition would happen over a 4-year period.

Additionally, CMS is proposing to:

- Accept most of the recommendations made by the PERC for the PE.
- Eliminate the HCPCS code for casting supplies and to include them in the PE database.
- Change the supply inputs for CPT code 95015
- Change the direct inputs for CPT code 88184 and 88185.
- No longer pay for HOCM under the PFS. Only "Q" codes will be accepted.
- Update "standardized rooms" in the equipment database
- Remove CPT codes 42550, 70370, 93508, 93510, and 93526
- Change the probe quantity in CPT 88367 to 1.5 for In situ Hybridization
- Update the fee for CPT codes 22520 and 22525
- Correct G0179 through G0182 which were incorrectly valued for clinical labor.
- Remove programmers for the implantable neurostimulators and intrathecal drug infusion pumps
- Update fees for supplies/equipment
- Request specialty input on certain supplies

B. Geographic Practice Cost Indices (GPCIs) (pp. 45783 -45784)

CMS is required to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components. While requiring that the practice expense and malpractice GPCIs reflect the full relative cost differences, the Act requires that the physician work GPCIs reflect only one quarter of the relative cost differences compared to the national average.

The MMA established a floor of 1.0 for the work GPCI for any locality where the GPCI would otherwise fall below 1.0. This 1.0 work GPCI floor is effective for dates of service after January 1, 2004 and before January 1, 2007.

The MMA set a floor of 1.67 for the work, practice expense, and malpractice GPCIs for services furnished in Alaska between January 1, 2004 and December 31, 2005 for any locality where the GPCI would otherwise fall below 1.67. Effective January 1, 2006, this provision will end and the proposed 2006 GPCIs for Alaska will be 1.017 for physician work, 1.103 for PE, and 1.029 for malpractice.

CMS proposed to change the 2006 GPCIs and GAFs for Santa Cruz County, Sonoma County and the Rest of California effective January 1, 2006 and asked for comments regarding this proposal, particularly from the California Medical Association.

The 2006 GPCIs by Medicare Carrier and Locality are listed in Addendum D and the 2006 GAFs are listed in Addendum E. The GPCIs and GAFs for Washington State are in the table below:

Carrier	Locality	Locality Name	2006 Work GPCI	2006 PE GPCI	2006 MP GPCI	2006 GAF
00836	02	Seattle (King Cnty), WA	1.014	1.131	0.819	1.058
00836	99	Rest of Washington	1.000	0.978	0.819	0.984

C. Malpractice Work RVUs (pp. 45784 – 45786)

As discussed in the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 final rule, CMS revised the resource-based malpractice expense RVUs using specialty-specific malpractice premium data because those data represent the actual malpractice expense to the physician and are widely available.

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Based on discussions with the medical community, CMS concluded that the primary determinants of malpractice liability costs are physician specialty, level of surgical involvement, and the physician's malpractice history.

This section discusses in detail the methodology used to calculate the malpractice RVUs.

In the 2005 Final Rule, CMS stated that they would continue to work with the AMA RUC's Professional Liability Insurance (PLI) Workgroup to address any potential inconsistencies that may still exist in the methodology. The RUC develops its recommendations based upon comments submitted to them by physician specialty organizations. The RUC PLI Workgroup provided all specialty societies and the HCPAC with the opportunity to submit comments on the crosswalks listed in the November 15, 2004 final rule.

The RUC PLI Workgroup recommendations and CMS's proposed decisions are outlined below.

RUC Recommendation	CMS Decision
The RUC PLI Workgroup recommends assigning a risk factor of 1.0 to the following professions because they believe the assigned risk factors overestimate their insurance premiums: • clinical psychology • licensed clinical social work • psychology • occupational therapy • opticians • optometrists • chiropractic • physical therapy	Proposing to implement RUC recommendation and solicits feedback.
The RUC PLI Workgroup recommends excluding the following professions that were assigned to the average for all physicians risk factor from the data used in the calculation of malpractice RVUs: • certified clinical nurse specialist (CNS), • clinical laboratory, • multispecialty clinic or group practice, • NP, • Physician assistant (PA), • and physiological laboratory (independent).	
Crosswalk CRNAs to anesthesiology (2.84) rather than "all physicians" (3.04)	Not accepting RUC recommendation but welcomes input.
Crosswalk colorectal surgeons to general surgery rather than using actual data	
Crosswalk gynecologists and oncologists to surgical oncology	
Correct RUC clerical error by adding the following CPT codes to the existing list of codes that should fall under the exception to apply a surgical risk factor to certain invasive cardiology catheterization and angioplasty codes: 92975; 92980 to 92998; and 93617 to 93641	Proposing to implement RUC recommendation and solicits feedback.
Use the dominant specialty approach for 1844 services with fewer than 100 occurrences	Not accepting RUC recommendation at this time, but will continue to work with the RUC PLI Workgroup to evaluate ways to ensure these low-volume services are not skewed by a few occurrences of aberrant data.

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D. Medicare Telehealth Services (pp. 45786 – 45788)

CMS outlined that in the December 31, 2002 Federal Rule, they established the process for adding or deleting services to the list of Medicare telehealth services. Since then, a psychiatric diagnostic interview exam and ESRD services with 2 to 3 visits per months and 4 or more visits per month have been added.

CMS has now received requests for Medical Nutrition Therapy and Diabetes Self-Management Training and is proposing to allow G0270, 97802, and 97803. However, they will not be allowing G0271, G0108, G0109, or 97804 .

CMS received a request to change their definition of a Interactive Telecommunications System and at this time they are still reviewing it and they are also reviewing whether or not to add SNFs as a telehealth originating site.

E. Contractor Pricing of Unlisted Therapy Modalities and Procedures (pp. 45788 – 45789)

Outlined the two unlisted procedure codes that have RVUs (97039 and 97139) may not be adequately providing reimbursement, or may be over reimbursing. Therefore, CMS is proposing that these be returned to contractor pricing.

F. Payment for Teaching Anesthesiologists (p. 45789)

Outlined payment for anesthesia services, and outlined the criteria for teaching physicians (the provider must be present with the resident for the critical or key portions of the service). CMS is requesting comments on a teaching physician policy for the anesthesiologists that could build on the current policy, but provide the appropriate revision that would allow it to be more flexible for teaching anesthesia programs. They would also like to see relevant data and studies regarding these issues.

G. End Stage Renal Disease (ESRD) Related Provisions (pp. 45789 – 45842)

CMS is proposing to:

- Revise the geographic classifications and wage indexes currently in effect for adjusting composite rate payments
- Revise the regulations applicable to the composite rate exceptions process to reflect section 623 of the MMA provisions that restricts exceptions to pediatric facilities.

CMS is proposing that that payment for a drug furnished in connection with a renal dialysis service and separately billed by freestanding renal dialysis facilities will be based on Section 1874 A of the Act and update the payment allowances quarterly based on the ASP reported by the drug manufacturers. Also, they are proposing to continue cost reimbursement for hospital-based facilities, while paying for EPO in hospital-based facilities at the ASP +6 percent.

CMS also outlined the adjustment to account for changes in the pricing of separately billable drugs and biologicals, and the estimated increased in expenditures for drugs and biologicals. They are proposing to calculate the CY 2006 drug add-on adjustment the same way as they did CY 2005 by calculating the spread based on the difference in aggregate payments between estimated payment based on AWP pricing and estimated payment based on ASP +6 pricing. They will be using pricing data from the second quarter of CY 2005, and will be updated for the final rule.

CMS completed its review of the current wage index. They are proposing to use OMB's revised geographic definitions and want to recalculate the ESRD wage indexes based on acute care hospital wage and employment date. They are also updating the labor portion of the ESRD composite rate to which the wage index is applied.

CMS is also proposing to revise Prospective Rates for Hospital-Based and Independent ESRD facilities by specifying that this subpart provides procedures and criteria under which only a pediatric facility may receive an exception and to reflect the changes in the additional payment for separately billable drugs.

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CMS is also proposing to revise the regulations by eliminating the other exception criteria outlined in 413.182 (b), (c), and (e) (isolated essential facilities, extraordinary circumstances, and frequency of dialysis), and followed this proposal up with an extensive in depth explanation of the proposed revisions.

H. Payment for Outpatient Drugs and Biologicals (pp. 45842 – 45849)

1. ASP Issues

In the first part of this section, CMS explains briefly its drug coverage and payment using the Average Sales Price (ASP) methodology.

a. Estimation methodology

CMS describes the current methodology for determining ASP which uses an average of direct and indirect sales to arrive at the price. CMS is proposing to modify the methodology to reduce the variation in pricing resulting from changing ratios of direct and indirect sales.

b. Price concessions: Wholesaler chargebacks

The modification would require manufacturers to calculate the ASP for direct sales separately from indirect sales and then calculate a weighted average of the two to report to CMS.

c. Determining the payment amount based on ASP data

CMS describes its methodology for converting manufacturers' ASP per NDC into the billing units used by CMS.

d. Reporting WAC

CMS is proposing to change the ASP reporting template to include a place to report wholesale acquisition cost (WAC). WACs must be reported when they are lower than the ASP and when the manufacturer has insufficient data to calculate the ASP.

e. Revised format for submitting ASP

- Drug name
- Package size
- Expiration date for last lot manufactured
- Date the NDC was first marketed (effective 10/1/05)
- Date of first sale for products first sold on or after 10/1/05

f. Limitations on ASP

CMS may ignore the ASP if the drug's widely available market price or average manufacturer's price is more than 5% lower than ASP. CMS is proposing to maintain 5% as the threshold for CY 2006.

2. Payment for drugs furnished during CY 2006 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities

CMS is proposing to pay ASP +6 to all free standing ESRD facilities for drugs separately billed by these facilities. In CY 2005, CMS paid for these drugs using acquisition costs.

3. Clotting factor furnishing fee

The furnishing fee for clotting factors, currently $.14, for years after CY 2005 must be increased by the increase in the medical CPI for the year ending the previous June. Since the CPI for the year ending June 2005 is not available, CMS will include the increase in the final rule.

4. Payment for inhalation drugs and dispensing fee

CMS explains how payment levels for CY 2005 were set and is seeking comments on what would be an appropriate dispensing fee for CY 2006. CMS is also seeking comments on the services necessary for providing inhalation drugs and how the new drug benefit might affect access.

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5. Supplying fee

CMS is proposing to change the supplying fee for covered oral immunosuppressive, chemotherapeutic and anti-emetic drugs to $24 for the first prescription (except for a $50 fee for an initial immunosuppressive drug post transplant) and $8 for each additional drug supplied during a month. Currently, CMS is paying $24 for each covered prescription supplied. CMS is also proposing to pay a separate supplying fee for each prescription filled on the same day for different strengths of the same drug. Currently, CMS only pays one supplying fee per drug dispensed regardless if there are multiple prescriptions or strengths.

I. Private Contracts and Opt-out Provisions (p. 45849)

CMS is proposing to amend the opt-out rules to clarify that the consequences for failure on the part of the physician or practitioner to maintain opt-out will apply regardless of whether or when a carrier notifies the provider of the failure to maintain opt-out. CMS is also proposing to add a paragraph to clarify that if the carrier discovers a violation after the 2 year opt-out period is over the consequences will be applied from the date of the first violation until the end of the opt-out period, unless the physician or practitioner makes a good faith effort to restore the conditions of opt-out within 45 days of carrier notice or within 45 days after the physician or practitioner discovers the failure to maintain opt-out, whichever is less.

J. Multiple Procedure Reduction for Diagnostic Imaging (pp. 45849 – 45851)

On January 1, 1995 Medicare began applying multiple procedure reductions to the following nuclear medicine diagnostic procedure codes: 78306, 78320, 78802, 78803, 78806, and 78807. (Although not mentioned in this Proposed Rule, Medicare discontinued the multiple procedure reduction for 78306 and 78320 in 2003.)

CMS is proposing to extend the multiple procedure payment reduction to the technical component of subsequent radiology procedures in 11 families of imaging procedures (see following table). The families are defined by imaging modality and contiguous body area. CMS believes that duplicate payment is currently being made for the technical component of multiple diagnostic imaging services, particularly when contiguous body parts are viewed in a single session.

Family #	Imaging Modality	Body Area	Codes in Family
Family 1	Ultrasound	Chest / Abdomen / Pelvis-Non-Obstetrical	76604-76778, 76830-76857
Family 2	CT and CTA	Chest / Thorax / Abd / Pelvis	71250-71275, 72191-72194, 74150-74175, 75635, 0067T
Family 3	CT and CTA	Head / Brain / Orbit / Maxillofacial / Neck	70450-70498
Family 4	MRI and MRA	Chest / Abd / Pelvis	71550-71555, 72195-72198, 74181-74185
Family 5	MRI and MRA	Head/Brain/Neck	70540-70553
Family 6	MRI and MRA	Spine	72141-72158
Family 7	CT	Spine	72125-72133
Family 8	MRI and MRA	Lower extremities	73718-73725
Family 9	CT and CTA	Lower extremities	73700-73706
Family 10	Mr and MRI	Upper extremities and joints	73218-73223
Family 11	CT and CTA	Upper extremities	73200-73206

K. Therapy Cap (p. 45851)

Beginning January 1, 2006, CMS will have a per beneficiary cap on outpatient physical therapy (PT) and speech-language pathology services and a similar cap on outpatient occupational therapy services.

The annual caps were initially added in the BBA of 1997, but were suspended from CY 2000 through 2002 and again from December 8, 2003 through December 31, 2005. The caps were active from September 1, 2003 through December 7, 2003.

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The Act provides that, for 1999 through 2001, the caps were both $1500, and for years after 2001, the caps are equal to the preceding year's cap increased by the percentage increase in the MEI (rounded to the nearest $10). Based on the April 4, 2005 MEI estimate, the estimated value of therapy caps for 2006 would be $1,750. CMS will publish the dollar amount for therapy caps in the final rule, when the MEI is available.

L. Chiropractic Services Demonstration (pp. 45851 – 45852)

Medicare's coverage for chiropractic services is currently limited to manual manipulation for the purpose of correcting a subluxation (using CPT codes 98940-98942). Medicare requires that the treatment be for an active subluxation, not for prevention or maintenance, and must be related to a neuromusculoskeletal condition where there is a reasonable expectation of recovery or functional improvement.

Medicare will be conducting a two year demonstration project in four sites (two rural, two urban and one of each an HPSA) to evaluate whether to expand coverage of chiropractic services to include diagnostic and other services. Details about services covered in the demonstration project were published in the January 28, 2005 Federal Register.

The demonstration will be budget neutral. Budget neutrality will be determined by looking at costs before and after the demonstration in the demonstration site areas and in control site areas. The analysis will not be limited to chiropractic claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs. Because CMS expects the claims analysis to take about two years, any necessary adjustments for budget neutrality will be applied to the chiropractor fee schedule in 2010 and 2011. If the adjustment is less than two percent, it will be implemented in one year, if it is greater than two percent, it will be implemented over two years. A detailed analysis of budget neutrality and the proposed offset will be published in the 2009 Federal Register publication of the PFS.

M. Supplemental Payments to Federally Qualified Health Centers (FQHCs) Subcontracting with Medicare Advantage Plans (pp. 45852 – 45853)

Medicare is required to provide supplemental payments to Federally Qualified Health Centers (FQHCs) that contract with Medicare Advantage (MA) plans. The supplemental payments augment the direct payments made by MA plans to FQHCs so that the FQHCs receive what they would otherwise receive under Medicare's cost-based all-inclusive payment rate.

To implement the payment provision, CMS must determine whether the Medicare cost-based payments that the FQHC would be entitled to exceed the amount of payments received from the MA organization and, if so, pay the difference to the FQHC at least quarterly. Medicare is precluded from including any financial incentives provided to the FQHCs under their MA arrangements (such as risk pool payments, bonuses or withholds) in the calculation of the supplemental payment.

For the first rate year calculation, the FQHCs will be required to submit estimates on the average MA payment per visit. This data will be used on an interim basis until the actual MA revenue and visits can be collected on the FQHCs cost reports; FQHCs will be required to report this information on their cost reports effective January 1, 2006. Payments will be made to the FQHC every time a face-to-face encounter occurs. Over or underpayments to the FQHC will be reconciled at the end of each cost reporting period based on the actual cost data.

N. National Coverage Decision Timeframes (p. 45853)

Amended so that under some circumstances the Board can modify the time frame to better reflect the actual time it will take.

O. Coverage of Screening for Glaucoma (pp. 45853 – 45854)

Limitations and screening for glaucoma has a specific eligible beneficiary list. This proposes to include Hispanic Americans age 65 and over. They would qualify for Medicare coverage and payment for glaucoma screening services if passed.

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P. Physician Referrals for Nuclear Medicine Services and Suppliers to Health Care Entities with which they have Financial Relationships (pp. 45854 – 45856)

A physician may not refer a Medicare patient for certain designated health services (DHS) to an entity with which the physician has a financial relationship. The rule does not currently include, but would with this change: Diagnostic and therapeutic nuclear medicine procedures for radiology and certain other imaging services and radiation therapy services and supplies.

Q. Sustainable Growth Rate (pp. 45856 – 45857)

This is not actually a proposed change but rather a request for input to reform the way physician fee schedules are updated under the SGR system. They are currently forecasting an update of -4.3% for 2006.

They explain the top 5 growth spending areas for 2004 and are looking for feedback to explain the reasons for the growth. And, they are particularly interested in comments that build on the recent progress on payment reforms to promote higher quality and avoid unnecessary costs.

III. Collection of Information Requirements (pp. 45857 – 45858)

CMS is required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

CMS is required to solicit comment on the need for the proposed information collection, the accuracy of CMS's estimate of the burden of the information collection requirement, the quality, utility and clarity of the information to be collected and any recommendations to minimize the information collection burden.

CMS solicited public comment on of the information collection requirements for pediatric ESRD facilities requesting an exception to payment rates and for manufacturers reporting ASP data to CMS.

IV. Response to Comments (p. 45858)

CMS will consider all comments received by 5 PM September 30, 2005, and will respond to the comments in the preamble to a subsequent document.

V. Regulatory Impact Analysis (pp. 45859 – 45875)

A. Resource-Based Practice Expense Relative Value Units (RVUs) (pp. 45859 – 45866)

CMS outlined the estimated impact on specialties due to changes in the PE methodology. The estimated payment impact reflects the averages for each specialty based on Medicare utilization, and CMS believes that much of the impact is due to the change in the scaling of the inputs when codes moved from the non-physician work pool to the individual specialty pool. Also, "the bottom up" methodology will help mitigate some of the potentially inequitable redistribution of PE RVUs resulting from the acceptance of new specialty-specific data. CMS is welcoming comments from Audiologists who had a significant impact with their removal from the non-physician pool.

CMS believes that the refined CPEP/RUC data is more accurate for calculating direct costs than the SMS or supplementary survey data; they are concerned that this is such a discrepancy between the refined direct cost inputs and a recent survey. CMS wants to follow up on this with the RUC and the specific specialty to ensure that they have received accurate information.

CMS is also proposing to:

- Remove the malpractice data for specialties that occur less than 5 percent in any given CPT.
- Accept recommendation from the RUC regarding several changes to the crosswalks used to assign risk factors to specialties for which they have no data
- Add cardiology catheterization and angioplasty codes to the list of codes for which we apply surgical rather than nonsurgical risk adjustment factors.

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- Reduce payments for technical components for certain multiple imaging procedures (multiple procedure reduction adjustment/discount) and they outlined the impact of this by family/provider groups

The impact of the proposed rule for selected procedures was outlined (these procedures are the most commonly billed among a wide spectrum of specialties). It also outlined the combined impact of PFS and the drug payment changes on the total revenues for specialties that perform a significant volume of drug administration services.

B. Geographic Practice Cost Indices (GPCI) - Payment Localities (pp. 45866 – 45867)

CMS proposed two changes to the California GPCI payment localities: 1) to remove both Santa Cruz County and Sonoma County from the Rest of California payment locality, and 2) to make both of those counties separate payment localities.

Compared to the Geographic Adjustment Factors (GAF) for 2005, the proposed changes would result in a 0.1% decrease to the GAF for the "Rest of California" locality and in increases of 10.6% and 8.5%, respectively, to the GAFs for Santa Cruz County and Sonoma County.

Table 36 shows the 2005 and proposed 2006 GPCIs and GAFs for all California payment localities.

C. Medicare Telehealth Services (p. 45868)

It is proposed that individual medical nutrition therapy be added to the list of telehealth services. The affected codes are G0270, 97802, and 97803. It is expected that these changes will have little effect on Medicare expenditures.

D. Contractor Pricing of CPT codes 97039 and 97139 (p. 45868)

It is proposed that the contractors value CPT codes 97039 and 97139, which will make the pricing methodology for these services consistent with the policy for other unlisted services. It is believed that this change will have no significant impact on Medicare expenditures.

E. End Stage Renal Disease (ESRD) Related Provisions (pp. 45868 – 45869)

To understand the impact of the proposed changes to the different categories of ESRD facilities, estimated payments under the current system have to be compared to estimated payments under the proposed revision to the composite rate payment system in the proposed rule.

Due to data limitations, CMS was unable to estimate current and proposed payments for 77 facilities. Providers were grouped into the categories based on characteristics provider in the Online Survey and Certification and Reporting (OSCAR) file, and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). Also CY 2004 Standard Analytical File (SAF) claims were used as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. CMS will update the SAF file once completed before the Final Rule is published. CMS enclosed a table outlining the impact of these proposed changes.

F. Payment for Covered Outpatient Drugs and Biologicals (p. 45869)

The proposal to pay a reduced supplying fee for each Medicare Part B oral drug prescription after the first one is supplied during a month, is estimated to reduce total expenditures by $8 million in 2006, and $30 million over the five-year period, CY 2006 to 2010. CMS is seeking comments to establish an appropriate inhalation drug dispensing fee amount for 2006. The impact on expenditures will be dependent on the dispensing fee amount that is established.

G. Private Contracts and Opt-out Provisions (p. 45869)

No significant impact.

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H. FQHC Supplemental Payment Provisions (p. 45869)

No significant impact.

I. National Coverage Decision Timeframes (p. 45869)

The proposal adapts certain timeframes to meet legislative changes made by the Medicare Modernization Act (MMA) of 2003. The changes will meet the Congressional intent with the development of national coverage decisions (NCD), and follows the regulation to the overall NCD process. There will be no budget implications as a result of these changes.

J. Coverage of Screening for Glaucoma (pp. 45869 - 45870)

Although this expanded benefit is expected to result in an increase in payments to ophthalmologists or optometrists providing this screening and related follow-up tests/treatment, it is not expected to have a significant cost impact on the Medicare program.

K. Physician Referral for Nuclear Medicine Services (p. 45870)

This proposed rule may result in savings by minimizing anti-competitive business arrangements as well as financial incentives that encourage over utilization of costly nuclear medicine services. CMS is unable to gauge with any certainty the extent of these savings to the Medicare and Medicaid programs at this time.

L. Alternatives Considered (p. 45870)

A range of policies, including some proposals related to specific MMA provision are discussed in the proposed rule. This includes descriptions of the statutory provisions addressed, identification of those policies when discretion has been exercised, rationale for decisions and, where relevant, addresses alternatives that were considered.

M. Impact on Beneficiaries (p. 45870)

Although there are a number of changes in this proposed rule that impact Medicare beneficiaries, CMS believes the changes will result in improved beneficiary access to services that are currently covered or expand the benefit package to include new services.

N. Accounting Statement (pp. 45870 - 45875)

An accounting statement prepared by CMS provides the classification of the expenditures associated with the provisions of this proposed rule. The impact of proposed changes on providers/suppliers encompasses an anticipated negative update to the physician fee schedule based on the statutory SGR formula. Expenditures are classified as transfers to providers/suppliers receiving payment under the physician fee schedule or Medicare Part B.

Addendum A – Explanation and Use of Addendum B (pp. 45876 – 45877)

Addendum B – Relative Value Units and Related Information (pp. 45878 – 46005)

Addendum C – Codes for Which We Received Practice Expense Review Committee (PERC) Recommendations on Direct Cost Inputs (p. 46006)

Addendum D – 2006 Geographic Practice Cost Indices (GPCI) by Medicare Carrier and Locality (pp. 46007 – 46008)

Carrier	Locality	Locality Name	2006 Work GPCI	2006 PE GPCI	2006 MP GPCI
00836	02	Seattle (King Cnty), WA	1.014	1.131	0.819
00836	99	Rest of Washington	1.000	0.978	0.819

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Addendum E – Proposed 2006 Geographic Adjustment Factors (GAFs) (p. 46009)

Carrier	Locality	Locality Name	2006 GAF
00836	02	Seattle (King Cnty), WA	1.058
00836	99	Rest of Washington	0.984

Addendum F – ESRD Facilities – Metropolitan Statistical Areas (MSA)/Core-Based Statistical Areas (CBSA) Crosswalk (pp. 46009 – 46056)

Reducing the supplying fee for drugs after the first one will reduce federal expenditures by $8 million in 2006 and $30 million over the five-year period 2006 - 2010. The effect on expenditures of possible changes to the dispensing fees for inhalation drugs will depend on the established amount.

Addendum G - List of CPT/HCPCS codes used to describe nuclear medicine designated health services under section 1877 of the Social Security Act (pp. 46056 – 46064)